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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/605, 577 06/28/00 WANG

W MSB-7267

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HM22/1024

EXAMINER

SEHARASEYON, J

ART UNIT PAPER NUMBER

1647 8

DATE MAILED:

10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/605,577	Wang et al.
	<b>Examiner</b>	<b>Art Unit</b>
	Sarada C Prasad	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 August 2001.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6,9 and 10 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6,9-10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

***Detailed Action***

1. Receipt of Applicants' arguments and amendments filed in Paper No. 7 (8/9/01) is acknowledged. Currently, claims 1-6, and 9-10 are under consideration.
2. The following previous rejections and objections are withdrawn in light of Applicants' amendments filed in Paper No. 7 (8/9/01).
  - (i) the objection to Oath and declaration;
  - (ii) the rejection of claims 1-6, 9-10 under 35 U.S.C. 102 (a) as anticipated by Shanafelt et al. (WO 996018 A1);
4. Applicant's arguments filed in Paper No. 7 (8/9/01), have been fully considered but were deemed persuasive in part. The issues remaining and new issues, are stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 103(a)***

6. Claims 1-6, 9-10 are rejected under 35 USC § 103(a) in Paper No.6 (3/13/01).

This rejection of record is being maintained for reasons of record set forth in the previous office actions (Paper No. 3, 10/26/00; Paper No.6, 3/13/01).

Applicants assert that the earlier office actions (Paper No. 3, 10/26/00; Paper No.6, 3/13/01) have been silent on the location of the suggestion in the prior art that would have motivated someone to combine the references ( page 3, 3<sup>rd</sup> para, lines 6-8, Paper No.7, 8/9/01). Further, Applicant also discusses at length the antibody nature of the protein that was stabilized in the citation used for the 103(a) rejection, Lee et al. (Paper No. 7, page 4, entire 3<sup>rd</sup> para). The response for both of these assertions would be as follows:

Compounds to achieve protein stabilization, such as sucrose, glycine, histidine, NaCl do not have any particular preference to any protein. Their function is to inhibit/lower proteolytic activity and therefore they can be employed for stabilization of any protein and motivation almost always is there for testing such possibility. A skilled artisan recognizes that one reason why a particular ingredient would be avoided in the protein stabilization mixture would be if it were needed in high enough concentration that even after several fold dilution, that ingredient would affect the processes that the stabilized polypeptide would be put to use.

Applicants also assert that ‘no suggestion in either of the references to delete essential components to make a new stabilizing compound. In fact, deletion of an element and retention of functionality is a clear indicia of unobviousness’ (Paper No. 7, 8/9/01, page 7, 1<sup>st</sup> para, lines 4-6). However, this argument is not persuasive because in all stabilization mixtures (column 3, summary of the invention, lines 9-end in U.S. Patent No. 5,874,408; column 2, summary of the invention, 3<sup>rd</sup> para, lines 5-end of U.S. Patent No. 5,078,997; instant claim 9, ranges of sodium chloride and glycine concentrations) each of the ingredients used are mentioned in what range they would be applicable, meaning that certain ingredients are also at ‘o’ concentration. The observed effects of such stabilizing mixtures when each ingredient is at its lowest concentration would provide the motivation for why any one component such as CaCl<sub>2</sub> should be eliminated. In fact, U.S. Patent No. 5,078,997 teaches that a stabilizer is selected from the group consisting essentially of: a mixture of arginine and carnitine....., or mixtures thereof, .....’ (column 2, summary of the invention, 2<sup>nd</sup> para, line 2 to the end of the paragraph).

Therefore, for one of skill in the art it is routine practice to test the different ranges of the said ingredients of the stabilizing mixtures for stabilizing effect and come to conclusion about the desirable/ beneficial effects of each of the constituents.

Therefore, the 35 USC 103(a) rejection of record for claims 1-6, and 9-10 is maintained.

*Conclusion*

1\$. No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1646

*Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS

October 20<sup>th</sup>, 2001

*Gary L. Kunz*  
GARY L. KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600